



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

CAU 1645
Box Sepu.

Applicant(s): Clark et al.
Serial No.: 09/497,967
Confirmation No.: 8124

Group Art Unit: 1645
Examiner: I. Fields
Docket No.: 235.0017 0101

RECEIVED

AUG 09 2001

Filed: February 4, 2000

Title: DIAGNOSTIC AND PROTECTIVE ANTIGEN GENE SEQUENCES OF
ICHTHYOPHTHIRIUS

TECH CENTER 1600/29

Assistant Commissioner for Patents
Washington, D.C. 20231

We are transmitting the following documents along with this Transmittal Sheet (which is submitted in triplicate):

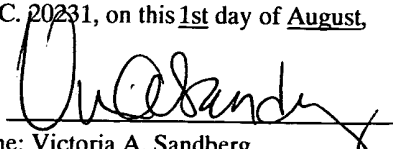
- ☒ **Small entity status is entitled to be asserted in the above-identified application.**
☒ An itemized return postcard.
☐ A Petition for Extension of Time for __ month(s) and a check in the amount of \$__ for the required fee.
☐ An Information Disclosure Statement (__ pgs); copies of __ applications; 1449 forms (__ pgs); and copies of __ documents cited on the 1449 forms.
☐ A certified copy of a __ application, Serial No. __, filed ____, the right of priority of which is claimed under 35 U.S.C. §119.
☒ Other: Response to Restriction Requirement, Preliminary Amendment and Communication Regarding Sequence Listing (3 pgs), computer readable form (CRF) of substitute Sequence Listing (one disk); paper copy of written substitute Sequence Listing (34 pgs) and copy of Notice to Comply (1 pg).
☐ Amendment __ No Additional fee is required. __ The fee has been calculated as shown:

Fee Calculation for Claims Pending After Amendment					
	Pending Claims after Amendment (1)	Claims Paid for Earlier (2)	Number of Additional Claims (1-2)	Cost per Additional Claim	Additional Fees Required
Total Claims				x \$9 =	
Independent Claims				x \$40 =	
One or More New Multiple Dependent Claims Presented? If Yes, Add \$135 Here →					
Total Additional Claim Fees Required					

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 13-4895. Triplicate copies of this sheet are enclosed.

CERTIFICATE UNDER 37 C.F.R. §1.8: The undersigned hereby certifies that this Transmittal Letter and the paper(s), as described hereinabove, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on this 1st day of August, 2001.

MUETING, RAASCH & GEBHARDT, P.A.
Customer Number: 26813

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(SMALL ENTITY TRANSMITTAL UNDER RULE 1.8)



PATENT
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TECH CENTER 1600/2900

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**RESPONSE TO RESTRICTION REQUIREMENT,
PRELIMINARY AMENDMENT AND
COMMUNICATION REGARDING SEQUENCE LISTING**

Assistant Commissioner for Patents
Washington D.C. 20231

Dear Sir:

In response to the Communication mailed July 3, 2001, please amend the specification to delete the written sequence listing and insert therefor the substitute sequence listing submitted herewith.

RESTRICTION REQUIREMENT

In response to the Restriction Requirement mailed July 3, 2001, Applicants elect, with traverse, the invention of Group I (claims 1-11, 14-21 and 23). The Examiner further restricted Groups I-VI according to MPEP 803.04, which recites that nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another, and required the Applicants to elect a single nucleotide sequence or protein sequence for examination. Applicants elect, with traverse, nucleotide sequences encoding at least a portion of SEQ ID NO:7. The Examiner further required the Applicants to elect either a 55 kDa i-antigen protein or a 48 kDa i-antigen or the DNA encoding one of the antigens for examination. Applicants elect, with traverse, DNA encoding at least a portion of a 55 kDa i-antigen protein.

Reconsideration and withdrawal or modification of the restriction requirement is respectfully requested. In particular, the Applicants request that the restriction requirement be

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modified to remove the requirement that the Applicants elect a single nucleotide or protein sequence for examination, and either a 55 kDa or a 48 kDa i-antigen protein. Applicants submit that it would not unduly burden the Office to allow the election of SEQ ID NO:6 as well as SEQ ID NO:7 for purposes of examination.

MPEP 803.04 does state that nucleotide sequences encoding different proteins normally constitute independent and distinct inventions. However, in recognition of the obstacle this position presents in any effort to obtain meaningful patent protection for biotechnology inventions, MPEP 803.04 goes on to state that "...to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of 37 C.F.R. 1.141 *et seq.*, and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996)."

MPEP 803.04 states that up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. Only in exceptional cases, when the nature of the claimed material is complex (for example, protein amino acid sequences reciting three dimensional folds) is it necessary that the reasonable number of sequences to be selected be less than ten. Applicants submit that the nucleotide and protein sequences recited in the present application are not characterized by any particular complexity that would make it burdensome to the Office to examine more than one at a time.

Accordingly, Applicants request that the Restriction requirement be reconsidered and withdrawn or modified such that the Applicants are permitted to elect SEQ ID NO:6 as well as SEQ ID NO:7 for purposes of the examination of the claims of Group I.

SEQUENCE LISTING

The substitute sequence listing submitted herewith contains mandatory keywords to SEQ ID NOS:31, 32, 33, 34, 88 and 89, that were not included in the sequence listing originally filed with the instant application. The substitute sequence listing contains no new matter.

In accordance with 37 C.F.R. §1.821, a computer readable form (CRF) and written Sequence Listing for the above-captioned application are submitted herewith. Applicants

**Response to Restriction Requirement,
Preliminary Amendment and Communication
Regarding Sequence Listing**

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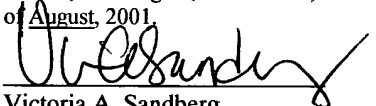
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respectfully request entry of same into the specification. A copy of the Notice to Comply that accompanied the Restriction Requirement mailed on July 3, 2001, is attached.

In accordance with 37 C.F.R. §1.821, it is respectfully submitted that the information recorded in computer readable form (CRF) of the Substitute Sequence Listing is identical to the written Substitute Sequence Listing filed herewith.

The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number if prosecution of this application may be assisted thereby.

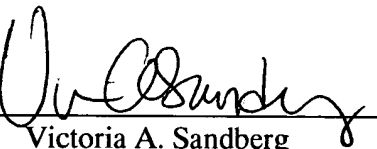
CERTIFICATE UNDER 37 C.F.R. 1.8:
The undersigned hereby certifies that this paper is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on this <u>1st</u> day of <u>August</u> , 2001.
 Victoria A. Sandberg

Respectfully submitted,

Clark et al.

By their Representatives,
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August 1, 2001
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